V. 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

K945627

GENERAL INFORMATION

Device Name:	
Proprietary Name	Pikos LP 01, Pikos LP E01
Classification Name	Implantable Pacemaker Pulse Generators
Device Classification:	Class III (21 CFR 870.3610)
Manufacturer:	BIOTRONIK GmbH & Co. Woermannkehre 1 D-12359 Berlin Germany Registration No.: 7010992
Applicant's Name & Address:	BIOTRONIK, Inc. 6024 Jean Road Lake Oswego, OR 97035
Establishment Registration No.:	1028232
Performance Standards:	No applicable performance standards have been promulgated for these devices.

DESCRIPTION OF DEVICE

The Pikos LP 01/LP E01 is a multi-programmable single chamber pulse generator which is designed and recommended for use with atrial or ventricular leads. The Pikos LP 01/LP E01 models offer a limited number of programmable options compared to those of the Pikos 01/E01 models.

SUBSTANTIAL EQUIVALENCE

The Pikos LP 01/LP E01 pulse generators are substantially equivalent to the currently marketed Pikos 01 and Pikos E01 respectively (K914109/A, approved February 26, 1992). Data to support this statement is provided in the premarket notification.

1 of 1

INTENDED USE

The Pikos LP 01/LP E01 models, like the Pikos 01/E01 models, are indicated for use in the following conditions:

- Sinus node arrest or bradycardia with or without AV conduction disorder.
- Intermittent or complete AV conduction block.
- Brady/tachy syndrome or other manifestation of sick sinus syndrome which results in symptomatic bradycardia.
- Atrial fibrillation and ventricular bradyarrhythmia.

QUALIFICATION TESTING

Qualification testing for the Pikos LP 01/LP E01 models is provided in this submission with the exception of battery qualification data which is identical to that submitted in the Pikos 01/E01 premarket notification (K914109/A). Qualification reports describing the testing conducted for validation of the self-sealing header are included in this submission. The qualification of the self-sealing header included vibration, shock, temperature and transport tests; tests meeting the applicable IS-1 requirements; header leakage resistance tests. Sterilization of the self-sealing header was validated. Hybrid circuit modifications were qualified with complete electrical and mechanical testing.

LABELING

Proposed labeling for the Pikos LP 01/LP E01 models is included in the premarket notification. The product labeling includes instructions for use adequate to assure safe and effective operation of the device.

195